PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2099.00022	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/36565	International filing date *(day/month/year)* 03 November 2004 (03.11.2004)	Priority date *(day/month/year)* 03 November 2003 (03.11.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 5/00 and US Cl.: 600/309,322		
Applicant CHILDREN'S MEDICAL CENTER CORPORATION		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 10 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 25 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I — Basis of the report
   - ☐ Box No. II — Priority
   - ☒ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV — Lack of unity of invention
   - ☒ Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI — Certain documents cited
   - ☒ Box No. VII — Certain defects in the international application
   - ☒ Box No. VIII — Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27 June 2005 (27.06.2005)	21 October 2005 (21.10.2005)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Max Hindenburg Telephone No. (571) 272-3000

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☐ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:
pages NONE as originally filed/furnished
pages* 1-23 received by this Authority on 27 June 2005 (27.06.2005)
pages* NONE received by this Authority on _____

☒ the claims:
pages NONE as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* 24 and 25 received by this Authority on 27 June 2005 (27.06.2005)
pages* NONE received by this Authority on _____

☒ the drawings:
pages 1-7 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 2-10

because:

☒ the said international application, or the said claim Nos. 2-10 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

Claims 2-10 constitute "use" claims that state no more than the use of an element. The claims are directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1,11-16	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1,11-16	NO
Industrial Applicability (IA)	Claims 1,11-16	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1 and 11-16 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 6,122,536 to Sun et al. Sun discloses an *in vivo* analyte-monitoring device capable of being used in continuously monitoring at least one analyte within a bodily fluid bypass flow path (figs. 1, 2, 4;; col. 9, line 52-54; col. 9, line 66-col. 10, line 3; col. 10, line 39-col. 11, line 21; col. 11, line 65-col. 12, line 1 of Sun).

As to the language "for use in continuously monitoring at least one analyte in the presence of an analyte within a bodily fluid bypass flow path" on lines 1-2 of claim 1 and the types of bypass flow paths listed in claim 10, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over Sun, since the reference teaches all of the claimed elements and their recited relationships. Note that the bodily fluid bypass flow path is not positively claimed and therefore is not included in the invention. The invention of Sun is clearly capable of use with a bypass flow path.

Regarding claims 11-16, Sun further discloses a method of using the apparatus described above, wherein the apparatus is capable of monitoring multiple analytes (col. 11, line 58-col. 12, line 8 of Sun).

Regarding claim 12-16, the amount of analytes detected by the sensor means is monitored, thereby monitoring any change in the amount of analytes, and compared to set norms. AA pump 16 responds to the detected mount of analytes outside the norms by administering at least one compound to the patient to bring the amount of analytes back to the range of the set norms, wherein eh compound may be insulin (col. 20, line 66-col. 21, line 7 of Sun).

Claim 11 lacks novelty under PCT Article 33(2) as being anticipated by US Patent No. 4,619,269 to Cutler et al. Cutler teaches a method of monitoring analytes in a bodily fluid (respiratory gas) of a patient within a bodily fluid bypass flow path (figs. 1-3; col. 3, lines 46-64; col. 4, line 63-col. 5, line 2 of Cutler).

Claims 11, 12, and 16 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 5,5757,643 to Wong et al. Wong describes a method of monitoring analytes present in a bodily fluid (blood) of a patient within a bodily fluid bypass flow path (figs. 1 & 2; col. 3, line 1-11 of Wong).

Regarding claim 12, the amount or concentration of analytes detected is monitored and compared to set norms (col. 4, lines 52-65 of Wong). Regarding claim 16, the monitoring step includes monitoring changes in the amount of analytes.

Claims 1 and 11-16 meet the criteria set forth in PCT Article 33(4) because the claimed subject matter can be made and/or used in industry.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 1 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof:
At the beginning of line 2 of claim 1, "at least one analyte" should be deleted;

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-16 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1-11 are indefinite for the following reason(s):

Claim 1 claims a monitoring device without delimiting any elements or structure of the device. The scope of the claim is therefore unclear.

Claims 11-16 are indefinite because claim 11 recites a method with reciting any active, positive steps delimiting how this use is actually practiced, therby making unclear the scope of the claim.